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EXAMINER

GEDEON, BRIAN T

ART UNIT	PAPER NUMBER
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3766

DATE MAILED: 11/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/804,780	<b>Applicant(s)</b> WANASEK ET AL.	
	<b>Examiner</b> Brian T. Gedeon	<b>Art Unit</b> 3766	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 March 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4-12,15-21,23,25,27-31,35-37,39 and 40 is/are rejected.
- 7) ☒ Claim(s) 2,3,13,14,22,24,26,32-34 and 38 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>4/26/04 and 7/7/04</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### ***Drawings***

The drawings are objected to because they seem to be informal, please see attached form PTO-948. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 5, 6, 7, 16, 17, and 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claimed "smoothing element" in each of the above claims lacks sufficient explanation within the specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 4 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: structure and means for generating the rotating multidimensional waveform.

3. Claims 29 and 37 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The claims mentioned fail to further limit the method claim they depend on by lacking additional method steps and only providing structure.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 10, 23, 29, and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Adams et al. (US Patent no. 5,441,518).

In regards to independent claims 1 and 23, Adams et al. discloses an implantable defibrillator capable of selectively configuring three or more implantable electrodes into a wide variety of discharge pathways for the electrical field of a cardioversion or defibrillation shock, column 3 lines 30-33. The system includes dual capacitors 66 and

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68 for energy storage, column 8 lines 65-66; a switch circuit 21 contains as many switches to provide control to however many electrodes are used, column 6 lines 7-9; said switch circuit 21 consists of a plurality of sets of switches 31, 32, 33, 34, 35, 36, 37, and 38; a programmable switch control 13 determines the desired discharge pathway selection by opening and/or closing said switches providing the necessary current flow capacitor 19 to the electrodes placed in the heart, column 6 lines 21-25.

In regards to dependent claims 10 and 29, Adams et al. teaches that it is well-known in the art that there are various forms of electrical energy transducers used for applying electricity to the heart, these can include epicardial surface electrodes, column 2 lines 7-9, intravenous electrodes, column 2 lines 16-17, and subcutaneous patch electrodes, column 2 line 24. Further, various implantable cardioversion/defibrillation devices contemplate using combinations of the above, column 2 lines 33-34.

In regards to independent claim 40, Adams et al. discloses an implantable defibrillator capable of sensing cardiac events by means of sensing electrodes 28, and can detect cardiac arrhythmias, providing the diagnostic input to independently programmable switch control 13, column 6 lines 27-30. A switch circuit 21 consists of a plurality of sets of switches 31-38; a programmable switch control 13 determines the desired discharge pathway selection by opening and/or closing said switches providing the necessary current flow capacitor 19 to the electrodes placed in the heart, column 6 lines 21-25.

5. Claim 39 rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Altman et al. (US Patent no. 4,726,379).

It would be obvious if not inherent to assume that the system of Altman is programmed to recognize pre-determined rhythms in the sensed cardiac signals since it delivers stimulating pulses to the heart based upon sensed cardiac signals in accord with any numerous known programs or procedures, column 11 lines 20-23. The pacer further comprises a controller 18 for controlling each of the switched capacitor circuits, column 4 lines 49-51. The controlled capacitor circuit 54A has at least one capacitor and at least two controlled switches, column 7 lines 19-22. The controller 18 can simultaneously open and close the switches, column 7 lines 33-34 and 39-41, so that the charge stored on the capacitor can be output onto the electrodes of the system. Further, a microcontroller 30 includes memory storage and a programmed microprocessor that can operate in different modes, column 12 lines 15-17. The Examiner considers this to be a computer readable medium having computer-executable instructions for performing the above method.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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6. Claims 5, 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (US Patent no. 5,441,518) in view of Persson (US Patent no. 5,405,361).

In regards to claim 5, Adams et al describes the invention as claimed except the smoothing element in series with the energy storage device. Persson shows in Figure 4, shows an inductor L1, which the Examiner recognizes as art relevant equivalent to a "smoothing element", in series with a capacitor Cn, which is recognized as a art relevant equivalent to an "energy storage device." Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a smoothing element in series with the energy storage element as a means for pulse shaping.

In regards to claim 6, Adams et al. describes the claimed invention except for the diode in parallel with the "smoothing element." Persson shows in Figure 4, a diode in parallel with the inductor, which is recognized as a "smoothing element." Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to place a diode in parallel with the smoothing element so that the energy stored in the magnetic field of the inductor returns to the source capacitor when current flow is interrupted by opening the switch.

In regards to claim 7, Adams et al. shows the energy storage capacitor 19 in parallel to a plurality of switching elements 31-38. Persson shows the energy storage capacitor in series with a "smoothing element" L1 and parallel with a switch S3a. It would have been obvious to one of ordinary skill in the art at the time the invention was made to insert another "energy storage device" such as a capacitor between the

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switches and inductor in order to receive excess stored energy from the magnetic field of the inductor when the switches open.

7. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (US Patent no. 5,441,518) in view of Ware et al. (US Patent no. 6,668,193).

Adams et al. describes the invention substantially as claimed including the housing referred to as the pulse generator can 11 which contains within a storage capacitor 19, an independently programmable switch control circuit 13; the switch circuit 21, and a pulse generator can electrode 12. However, Adams et al. does not describe the placement of the electrodes. Ware et al. discloses a method and apparatus for cardiac shock therapy comprised of a storage capacitor C1 and a plurality of electrodes, 52a-42c. In one embodiment of Ware et al. is comprised of a first distal electrode placed in the right ventricle, and second and third shocking electrodes placed in the superior vena cava and coronary sinus respectively, column 4 lines 58-67. Further, another arrangement may be made when the housing canister is used as one electrode, while other electrodes may be implanted in the superior vena cava, the coronary sine, and the right ventricle, column 5 lines 5-9. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to position the electrodes accordingly in order to delivery shock therapy to all parts of the heart.

8. Claims 11, 12 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (US Patent no. 5,441,518) in view of Rubin et al. (US Patent no. 6,298,266).



Adams et al. substantially describes the claimed invention except for the time delay associated with the switches. Rubin et al. describes a method and apparatus for treating fibrillation and creating defibrillation waveforms that involve a time delay between the first pulse 278 and the second pulse 280. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to implement a time delay between discharge of the capacitor in order to form discrete sequential output pulses.

In regards to claim 12, Rubin et al. teaches that the time delay is determined by the frequency of the pulse width modulated signal delivered to the switch 266. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to since it was known in the art to use a switch to implement a time delay in order to create a discrete set of electrical pulses.

In regards to claim 21, Adams et al. teaches that it is well-known in the art that there are various forms of electrical energy transducers used for applying electricity to the heart, these can include epicardial surface electrodes, column 2 lines 7-9, intravenous electrodes, column 2 lines 16-17, and subcutaneous patch electrodes, column 2 line 24. Further, various implantable cardioversion/defibrillation devices contemplate using combinations of the above, column 2 lines 33-34.

9. Claims 16, 17, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (US Patent no. 5,441,518) in view of Persson (US Patent no. 5,405,361) and Rubin (US Patent no. 6,298,266).

In regards to claim 16, Adams et al describes the invention as claimed except the smoothing element in series with the energy storage device. Persson shows in Figure 4, shows an inductor L1, which the Examiner recognizes as art relevant equivalent to a "smoothing element", in series with a capacitor Cn, which is recognized as a art relevant equivalent to an "energy storage device." Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a smoothing element in series with the energy storage element as a means for pulse shaping.

In regards to claim 17, Adams et al. describes the claimed invention except for the diode in parallel with the "smoothing element." Persson shows in Figure 4, a diode in parallel with the inductor, which is recognized as a "smoothing element." Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to place a diode in parallel with the smoothing element so that the energy stored in the magnetic field of the inductor returns to the source capacitor when current flow is interrupted by opening the switch.

In regards to claim 18, Adams et al. shows the energy storage capacitor 19 in parallel to a plurality of switching elements 31-38. Persson shows the energy storage capacitor in series with a "smoothing element" L1 and parallel with a switch S3a. It would have been obvious to one of ordinary skill in the art at the time the invention was made to insert another "energy storage device" such as a capacitor between the switches and inductor in order to receive excess stored energy from the magnetic field of the inductor when the switches open.

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10. Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (US Patent no. 5,441,518) and Rubin et al. (US Patent no. 6,298,266) in view of Ware et al. (US Patent no. 6,668,193).

Adams et al. and Rubin et al. describe the invention substantially as claimed including the housing referred to as the pulse generator can 11 which contains within a storage capacitor 19, an independently programmable switch control circuit 13; the switch circuit 21, and a pulse generator can electrode 12. However, Adams et al. does not describe the placement of the electrodes. Ware et al. discloses a method and apparatus for cardiac shock therapy comprised of a storage capacitor C1 and a plurality of electrodes, 52a-42c. In one embodiment of Ware et al. is comprised of a first distal electrode placed in the right ventricle, and second and third shocking electrodes placed in the superior vena cava and coronary sinus respectively, column 4 lines 58-67.

Further, another arrangement may be made when the housing canister is used as one electrode, while other electrodes may be implanted in the superior vena cava, the coronary sine, and the right ventricle, column 5 lines 5-9. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to position the electrodes accordingly in order to delivery shock therapy to all parts of the heart.

11. Claims 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (US Patent no. 5,441,518) in view of Ware et al. (US Patent no. 6,668,193).

Adams et al. describes the invention substantially as claimed including the housing referred to as the pulse generator can 11 which contains within a storage

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capacitor 19, an independently programmable switch control circuit 13; the switch circuit 21, and a pulse generator can electrode 12. However, Adams et al. does not describe the placement of the electrodes. Ware et al. discloses a method and apparatus for cardiac shock therapy comprised of a storage capacitor C1 and a plurality of electrodes, 52a-42c. In one embodiment of Ware et al. is comprised of a first distal electrode placed in the right ventricle, and second and third shocking electrodes placed in the superior vena cava and coronary sinus respectively, column 4 lines 58-67. Further, another arrangement may be made when the housing canister is used as one electrode, while other electrodes may be implanted in the superior vena cava, the coronary sine, and the right ventricle, column 5 lines 5-9. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to position the electrodes accordingly in order to delivery shock therapy to all parts of the heart.

12. Claims 30, 31, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (US Patent no. 5,441,518) in view of Rubin et al. (US Patent no. 6,298,266).

Adams et al. substantially describes the claimed invention except for the time delay associated with the switches. Rubin et al. describes a method and apparatus for treating fibrillation and creating defibrillation waveforms which involves a time delay between the first pulse 278 and the second pulse 280. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to implement a time delay between discharge of the capacitor in order to form discrete sequential output pulses.

In regards to claim 31, Rubin et al. teaches that the time delay is determined by the frequency of the pulse width modulated signal delivered to the switch 266.

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to since it was known in the art to use a switch to implement a time delay in order to create a discrete set of electrical pulses.

In regards to claim 37, Adams et al. teaches that it is well-known in the art that there are various forms of electrical energy transducers used for applying electricity to the heart, these can include epicardial surface electrodes, column 2 lines 7-9, intravenous electrodes, column 2 lines 16-17, and subcutaneous patch electrodes, column 2 line 24. Further, various implantable cardioversion/defibrillation devices contemplate using combinations of the above, column 2 lines 33-34.

13. Claims 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (US Patent no. 5,441,518) and Rubin et al. (US Patent no. 6,298,266) in view of Ware et al. (US Patent no. 6,668,193).

Adams et al. and Rubin et al. describe the invention substantially as claimed including the housing referred to as the pulse generator can 11 which contains within a storage capacitor 19, an independently programmable switch control circuit 13; the switch circuit 21, and a pulse generator can electrode 12. However, Adams et al. does not describe the placement of the electrodes. Ware et al. discloses a method and apparatus for cardiac shock therapy comprised of a storage capacitor C1 and a plurality of electrodes, 52a-42c. In one embodiment of Ware et al. is comprised of a first distal electrode placed in the right ventricle, and second and third shocking electrodes placed

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in the superior vena cava and coronary sinus respectively, column 4 lines 58-67.

Further, another arrangement may be made when the housing canister is used as one electrode, while other electrodes may be implanted in the superior vena cava, the coronary sine, and the right ventricle, column 5 lines 5-9. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to position the electrodes accordingly in order to delivery shock therapy to all parts of the heart.

#### ***Allowable Subject Matter***

14. Claims 2, 3, 13, 14, 22, 24, 25, 26, 32, 33, 34 and 38 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Conclusion***


15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kroll (US Patent no. 5,620,469) discloses a system for treating cardiac arrhythmias using a series of stepped cardioversion pulses. Hedberg (US Patent no. 5,376,105) discloses a cardiac defibrillator/cardioverter that generates output pulses, which temporarily overlap one another at different times and in different numbers. Stemple et al. (US Patent no. 4,566,457) discloses a defibrillator circuit and electrodes with energy storage means and plurality of switches.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian T. Gedeon whose telephone number is (571) 272 3447. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272 6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Robert E Pezzuto  
Supervisory Patent Examiner  
Art Unit 3766

BTG